REMARKS

Initially the Applicant and his representatives wish to thank Examiner Gambel for the courtesy extended in the personal interview of January 5, 2011. A brief summary of the interview is provided below.

During the personal interview, the Applicant reviewed with the Examiner the substance of the rejection of the claims in the Office Action based upon the six cited references, from each of which a teaching was selected and combined to reject claims 1, 2 and 4-12 under 35 USC § 103(a). During the interview, the Examiner made certain requests in connection with the application including, in particular, that a showing of support in the specification for the amended claims and new claims in Applicants' Amendment dated November 15, 2010 would be helpful. Other references to the discussions at the personal interview are addressed below.

GROUNDS OF REJECTION

1. Claims 1-2 and 4-12 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Curiel et al. (U. S. Patent No. 6,284,742) (829; of record) in view of Xiang et al. (J. Immunol. 167:4560-4565, 2001) (1449; #A91), Zheng et al. (Cancer Research 61:8127-8134m, 2001) (1449; #A96), Hu et al. (PNAS 96:8161-8166, 1999), Dreyfus et al. (US 2002/0068048), and Thomas et al. (US 2005/0048645).

2. Claim 3 was rejected under 35 U.S.C §103(a) on the above identified six references and the same combination of teachings and further in view of Lamikanra et al. (J. Virol. 75:9654-9664, 2001) (1449: #A63).

3. Claims 10 and 11 were rejected under 35 USC § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 10 and 11 were rejected as indefinite in reciting "residues 1-23 and 47-261" of CD40 ligand because the referenced sequence(s) (SEQ ID NO(S)) is (are) missing.

4. Claims 13-34 were withdrawn, with traverse, in a Response to the Restriction Requirement dated March 30, 2010, on the basis of a restriction requirement in the Office Action mailed October 5, 2009.

All pending claims stand rejected under 35 U.S.C. § 103(a).

SUPPLEMENTAL INFORMATION

1. Support for Amended Claims and New Claims

In Applicants' Amendment filed November 15, 2010, claims 1, 2, 4, 6, 9, 10, and 11 were amended and claims 35-42 were added.

During the course of the interview on January 5, 2011, Examiner Gambel suggested that it would be helpful if the Applicants indicated where support for amendments to claims 1, 2, 4, 6, 9, 10, and 11, as well as for newly added claims 35-42, could be found in the Applicants' specification. In accordance with the Examiner's suggestion, Applicants hereby provide information indicating where support for the amended claims and newly added claims 35-42 can be found in the Applicants' specification.

As to amended claim 2, the Examiner's attention is directed to the following sections of the specification which sections are submitted to provide support for this amended claim. See, for example, sections 0005, 0021, 0026, 0029, 0030, 0033, 0041, 0042, 0046, 0047, 0050, 0062, 0068, 0070, 0074, 0077, 0084, and 0086.

As to amended claim 4, the Examiner's attention is directed to the following sections of the specification which sections are submitted to provide support for this amended claim. See, for example, sections: 0041, 0046, 0062, 0070, 0074, 0084, and 0086.

As to amended claim 6, the Examiner's attention is directed to the following sections of the specification which sections are submitted to provide support for this amended claim. See, for example, sections: 0006, 0009, 0016, 0027, 0028, 0039, 0046, 0060, and 0093.

As to amended claims 10 and 11, the Examiner's attention is directed to the following sections of the specification which sections are submitted to provide support for the amended claims. See, for example, sections: 0030, 0031, 0032, 0033, and 0093. It is noted that the claims as amended are believed to be in compliance with the Examiner's rejection under 35 USC § 112, second paragraph. Further support for the claim language, with regard to Sequence ID Numbers, may be obtained, for example, from the Armitage patent (US Patent No. 5,962,406,) incorporated by reference in Applicants' specification at section 0030, and disclosed in the Armitage patent at Figures 1 and 2 and at the Summary of Invention at column 2 lines 42-62, of the Armitage patent including functionally similar sequences.

As to new claims 35, 36, and 38 the Examiner's attention is directed to the following sections of the specification which sections are submitted to provide support for the amended claims. See, for example, sections: 0027, 0028, 0046, 0053, and 0060.

As to new claims 37 and 39-42, the Examiner's attention is directed to the following sections of the specification which sections are submitted to provide support for the amended claims. See, for example, sections: 0014, 0020, 0021, 0041, 0042, 0044, 0045, 0047, 0048, 0049, 0060, 0062-0064, 0068, 0070, 0073-0078.

Accordingly, it is respectfully submitted that all of the amended claims and the new claims referred to above are amply supported by the specification.

2. Rejection of claims 1-12 under 35 USC § 103 and Supplemental Arguments in favor of claims 1-12 and new claims 35-42.

During the interview with the Examiner, Applicant reviewed with the Examiner Applicant's view of the prior art for the most part as advanced in Applicant's Amendment dated November 15, 2010.

Applicant reviewed with the Examiner each of the six references that were applied by selection of a teaching from each of the references and combining the six teachings on the basis of obviousness against Applicant's claims 1-12 under 35 USC § 103. With respect to the arguments made at the interview against the pending rejection, Applicant noted that the

Examiner may have had questions with respect to Applicant's comments concerning the Zheng reference.

As pointed out in Applicants' response as well as during the interview, Applicant believes that the Zheng reference is distinct from Applicants' claim 1. Zheng teaches the painting of the outer surface of the tumor cell using the complex system of two fusion proteins for the attachment of activators of a non-antigen specific immune response to the tumor cells. Therefore Zheng teaches the attachment of several immunostimulatory signals which are not antigen specific (see at page 8127 of Zheng under the abstract at lines 8-19). Zheng consists of making in vitro (outside the body) mixtures of tumor cells (the target) with the two separate and distinct fusion proteins.

For example, Zheng fails to teach use of an adenoviral expression vector carrying a transcription unit encoding the tumor antigen/ecdCD40L protein, the release of the protein from vector infected cells, which proteins activate and antigen load dendritic cells so that they are caused to migrate to lymph nodes where they encounter, activate and expand antigen specific CD8 effector T cells(see, for example, claims 37, 39, and 40-42), in effect solving the problem of presenting tumor antigens on Class I MHC (see also claim 2) by overcoming states of anergy and defective T cell helper function in immunocompromised subjects.

3. Unexpected and Surprising Result

Also, as pointed out by the Applicant and discussed at the interview, it is believed that the use and application of the product claimed, produced results that largely exceeded Applicants' expectations in terms of the strength and duration of the impact on tumor presenting cells. The experimentation disclosed in the specification underscores that the Applicants' expression vector product embodied by claim 1 produced a startling higher level of stimulation of the immune response and one which lasted for a considerable period of time due to expression or production from the infected cells following vector injection of the antigen/ecdCD40L fusion protein. As noted in sections 0027, 0028, 0039, 0040, 0048, 0049, and 0071, the claimed product demonstrated that implementation of the product in the TAA preferred embodiment by injection led to a very robust T cell dependent systemic immunity to cell lines carrying the tumor

associated antigen which not only showed that in a tumor challenge all the mice were free after 108 days, but further that test results demonstrated that the robust and long lasting extended tumor protection after the injection lasted for greater than one year.

4. Rejoinder of withdrawn Method Claims 13-34

It is respectfully submitted that in the event that the Examiner finds that Applicants' product claim 1 is allowable, it is respectfully requested that the withdrawn method claims 13-34 be rejoined with the allowed product claim and also be allowed.

CONCLUSION

For the reasons advanced above, in addition to the reasons advanced in Applicants' Amendment, Applicants respectfully submit that all of the pending claims are allowable. Accordingly, Applicants respectfully submit that the claims be considered to be in condition for allowance and that the withdrawn method claims additionally be rejoined and that these method claims also be considered as being in condition for allowance.

To the extent necessary, a petition for an extension of time under 37 CFR 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 50-4752 and please credit any excess fees to such deposit account.

Dated January 19, 2011

Respectfully submitted,

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